

Practitioner's Docket No. 56513 (45107)

IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

PCT/EP00/04360 16 May 2000 18 May 1999
INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED

A TRANSDERMAL THERAPEUTIC SYSTEM CONTAINING TOLTERODINE
TITLE OF INVENTION

Christoph ARTH, Claus MEESE, Dietrich Wilhelm SCHACHT AND Hans-Michael WOLFF
APPLICANT(S) FOR DO/US

Box PCT
Assistant Commissioner for Patents
Washington, D.C. 20231
ATTENTION: DO/US

COMPLETION OF FILING REQUIREMENTS
FOR INTERNATIONAL APPLICATION ENTERING NATIONAL
STAGE IN U.S. DESIGNATED OFFICE (DO/US) UNDER 35 U.S.C. 371

(check and complete the following item, if applicable)

- ☒ This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. 1.494 (FORM PCT/DO/EO/905).
☒ A copy of FORM PCT/DO/EO/905 accompanies this response.

WARNING: *Filing requirements, including translation of the international application, the declaration, the national fee and the payment of all the surcharge(s) in connection with the filing of these items after twenty (20) months from the priority may be met within twenty-two (22) months from the priority date. Failure to comply with these requirements Will result in abandonment. The provisions of 37 CFR 1.136 for extensions of time do not apply to the 22 month period. 37 CFR 1.61(b).*

CERTIFICATION UNDER 37 C.F.R. 1.10*
(Express Mail label number is **mandatory**.)
(Express Mail certification is optional.)

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date April 25, 2002, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL932681517US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan M. Dillon
(type or print name of person mailing paper)
Susan M Dillon
Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*
***WARNING:** *Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R 1.10(b).
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

NOTE: The completion of the filing requirements within 22 months (instead of 20 months) from the priority date results from the Commissioner exercising his judgment under the authority granted under 35 USC 371(d). The filing receipt will show the actual date of receipt of the last item completing the entry into the national phase. See 37 CFR 1.491 which states: "An international application enters the national stage when the applicant has filed the documents and fees required by 35 USC 371(c) within the periods set forth in § 1.494 and § 1.495."

WARNING: Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 20 months from the priority date, the application is still considered to be in the international stage. If mailing procedures are utilized to obtain a date, the express mail procedure of 37 CFR 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 CFR 1.8(2)(xi).

NOTE: Documents and fees must be clearly identified as a submission to enter the national stage under 35 USC 371. Otherwise, the submission will be considered as being made under 35 USC 111. 37 CFR 1.494(f).

DECLARATION OR OATH

I. ☒ [X] No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

NOTE: For surcharge fee for filing declaration after filing date, complete item IV(2).

NOTE: Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are the name of the inventor and (1) serial number, (2) attorney docket number that was on the application as filed and the filing date, (3) title of the invention and filing date, (4) title of invention and reference to a specification that is attached to the declaration at the time of execution and filed with the declaration, or (5) title of invention and a statement by a registered attorney that the application filed in the PTO is the application that the inventor executed by signing the declaration. If identification (4) is used, it must be accompanied by a statement that the "attached" specification is a copy of the specification and any amendments thereto that were filed in the PTO to obtain the filing date. Such a statement must be a verified statement if made by a person not registered to practice before the PTO. Notice of September 12, 1983 (1035 O.G. 3).

NOTE: Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 CFR 1.10(c).

NOTE: 37 CFR 1.41(a) points out that "Full names must be stated, including the family name and at least one given name without abbreviation together with any other given name or initial."

(complete (a) or (b), if applicable)

Attached is a

- (a) ☐ [] Statement by a registered attorney that the application filed in the PTO is the application that the inventor executed by signing the declaration.
- (b) ☐ [] Statement that the "attached" specification is a copy of the specification and any amendments thereto that were filed in the PTO to obtain the filing date.

AMENDMENT

II. (complete as applicable)

- ☐ [] An amendment in accordance with 37 C.F.R. § 1.121 is attached.
- ☐ [] The attached amendment cancels claims _____ inclusively.

**TRANSMITTAL OF ENGLISH TRANSLATION
OF NON-ENGLISH LANGUAGE PAPERS**

- III.** ☐ Submitted herewith, is a English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 CFR 1.494(b)(2)).

NOTE: For fee for processing a non-English application, complete item IV(4).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

NOTE: Unlike the filing of an ordinary non-English application (37 CFR 1.52(d) the translation of an international application entering the U.S. national phase need not be verified. 37 CFR 1.494(e). If necessary, however, a verified translation may be required. 37 CFR 1.494(e). Moreover, if the English translation is filed within 20 months from the priority date, no processing fee is required.

FEES

IV.

NOTE: See 37 CFR 1.28(a).

1. Fees for claims

- | | | |
|-------------------------------------|--|------------------|
| <input type="checkbox"/> | Each independent claim in excess of 3
(37 CFR 1.492(b) \$78.00; Small entity—\$39.00) | \$ _____ |
| <input type="checkbox"/> | Each claim in excess of 20
(37 CFR 1.492(c) - \$18.00; small entity—\$9.00) | \$ _____ |
| <input checked="" type="checkbox"/> | Multiple dependent claim(s)
(37 CFR 1.492(d) - \$280.00;
small entity—\$140.00) | \$ <u>280.00</u> |

2. Surcharge fees

- | | | |
|--------------------------|--|----------|
| <input type="checkbox"/> | Surcharge set forth in § 1.492(e), for accepting the declaration later than 20 months after the priority date in filing an application in the U.S. as a designated office— \$130.00;
small entity—\$65.00 | \$ _____ |
|--------------------------|--|----------|

NOTE: The processing fee in the next item (Number 3) below is not subject to a reduction for small entity status.

3.

- | | | |
|--------------------------|--|----------|
| <input type="checkbox"/> | Processing fee set forth in § 1.492(f), for acceptance of an English translation later than 20 months after the priority date—\$130.00 | \$ _____ |
|--------------------------|--|----------|

- | | | |
|-----------|--|-----------------|
| 7. | <input checked="" type="checkbox"/> Assignment (See "ASSIGNMENT COVER SHEET".) | \$ <u>40.00</u> |
|-----------|--|-----------------|

04/30/2002 GFREY1 00000120 10009644

01 FC:968

280.00 OP

Total fees \$ 320.00

SMALL ENTITY STATUS

V. A statement that this filing is by a small entity

NOTE: See 37 CFR 1.28(a).

(check and complete applicable items)

- a. ☐ is attached.
was filed on _____ (original).
b. ☐ A separate refund request accompanies this paper.

EXTENSION OF TIME

(complete (a) or (b), as applicable)

VI.

The proceedings herein are for a patent application. The provisions of 37 C.F.R. § 1.1 36(a) apply.

- (a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below:

Extension (months)	Fee for over than small entity _____	Fee for small entity
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 400.00	\$200.00
<input type="checkbox"/> three months	\$ 920.00	\$460.00
<input type="checkbox"/> four months	\$1,440.00	\$720.00
		Fee \$ _____

If an additional extension of time is required, please consider this a petition therefore.

(check and complete the next item, if applicable)

- ☐ An extension for _____ months has already been secured. The fee paid therefor of \$ _____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ _____.

or

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

TOTAL FEE DUE

VII. The total fee due is:

Completion fee(s) \$ 320.00
Extension fee (if any) \$ _____

TOTAL FEE DUE \$ 320.00

PAYMENT OF FEES

VIII.

☒ Enclosed is a check in the amount of \$ 280.00 and \$40.00.
☐ Charge Account No. _____ in the amount of \$ _____.
A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

AUTHORIZATION TO CHARGE ADDITIONAL FEES

IX.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges.

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 CFR 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 CFR 1.26(a).

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper, and during the entire pendency of this application, to Account No. 04-1105
☒ 37 C.F.R. 1.492(a)(2), 1.492(a)(3), or 1.492(a)(5) (filing fees)
☒ 37 C.F.R. 1.492(b) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing, or on later presentation, must only be paid, or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☒ 37 C.F.R. 1.17 (application processing fees)
☒ 37 C.F.R. 1.17(a)(1)-(5)(extension fees pursuant to § 1.136(a).

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a "quest or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

☐ 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311 (b)).

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity

[] 37 C.F.R. 1.492(e) and (f) (surcharge fees for filing the declaration and/or an English translation of an international application later than 20 months from the earliest claimed priority date)

WARNING: It is suggested that you always check this last authorization.



SIGNATURE OF PRACTITIONER

Reg. No. 33,860

Peter F. Corless
(type or print name of practitioner)

Tel. No.: (617) 439-4444

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P.O. Box 9169
P.O. Address

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UNITED STATES PATENT AND TRADEMARK OFFICE

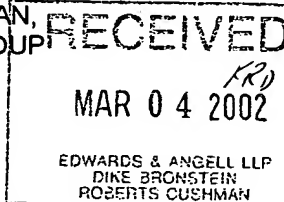
Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/009,644	Christoph Arth	56513 (45107)

INTERNATIONAL APPLICATION NO.
PCT/EP00/04360

21874

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I.A. FILING DATE	PRIORITY DATE
05/16/2000	

CONFIRMATION NO. 9674

371 FORMALITIES LETTER



OC00000007524326

Date Mailed: 02/25/2002

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Information Disclosure Statements
- Request for Immediate Examination

File Missing PARTS

Edwards & Angell LLP
Dike, Bronstein, Roberts & Cushman
101 Federal St. Boston, MA 02110

Date Rec'd 3/4/02Docketed For Apr. 25 - Aug. 25, 2002By KRD

Approved _____

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Additionally the following defects have been observed:

- Additional claim fees of \$280 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees

are due.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$280 for a Large Entity:

- Total additional claim fee(s) for this application is \$280
 - \$280 for multiple dependant claims surcharge.

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

LAMONT M HUNTER

Telephone: (703) 305-3686

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/009,644	PCT/EP00/04360	56513 (45107)